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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Olivier LUHN. Group art unit :1711

Serial No.: 09/905,569

Filed: July 13, 2001

Assigned to: ROQUETTE FRERES

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on October 9, 2001

Hodges Conrad

FOR: GRANULES BASED ON STARCH AND LACTOSE.

INFORMATION DISCLOSURE STATEMENT

To the Honorable Commissioner of Patents and Trademarks  
Washington, D.C.

Sir :

In accordance with the duty of disclosure set forth in 37 C.F.R. § 1.56 and pursuant to 37 C.F.R. 1.97-1.99 the Applicant hereby submits:

(a) a list of prior art referred to by the Applicant in the specification of the application and/or which has been cited in the Search Report prepared by the European Patent Office in respect of the corresponding European Application No.00.402.159.8;

(b) a copy of this Search Report attached in order to inform the U.S. Examiner of the first opinion of the Examiner of the European Patent Office, and those portions of the references found pertinent by the latter;

(c) a copy of the references cited under (a) namely:

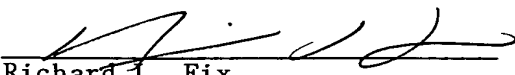
- GB 833.458 A (ROHM & HAAS COMPANY),
- GB 2.093.052 A (GERGELY GERHARD),

- HILL PM: "STARCH PASTE GRANULATIONS..."Journal of Pharmaceutical Sciences, vol. 65, no. 2, 1976, pages 313-314,
- Tadashi MAKINO et al : "IMPORTANCE OF GELATINIZATION DEGREE OF STARCH PAST..." Chemical and Pharmaceutical Bulletin, JP, vol. 43, no. 3, 1 mars 1995, pages 514-516,
- VISAVARUNGROJ N et al : "CROSSLINKED STARCH AS BINDING AGENT I. CONVENTIONAL WET GRANULATION" International Journal of Pharmaceutics, vol. 59, no.1, 1990, pages 73-78,
- US 5.618.562 in lieu of DE 44.00.295 A (FREUND IN CO LTD),
- US 5.006.345 A (LANG SIEGFRIED),
- M.O. Bode-Tunji and K.T. Jaiyeoba : "The effect of starch and surfactants on the granulation of soluble and insoluble powders, 1984, p 190-192,
- L.S.C. Wan and K.D Lim : "Granulation of mixtures of lactose and starch by a fluidized bed technique", 1991, p 285-293,
- A. Stamm and C. Mathis : "Les excipients pour compression directe", 1976, p 237-246, and English translation of its relevant parts,
- Extrait de la Pharmacopée, 1997, p 1111-1112, and its partial English translation.

October 9, 2001

Respectfully submitted.

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|---|---|---|-----------------------|------------------------------|-------|--------------|-------------------------------|
| <b>INFORMATION<br/>DISCLOSURE CITATION</b><br><br>(Use several sheets if necessary)   |   | ATTY. DOCKET<br>No.   |                       | SERIAL No. <b>09/905,569</b> |       |              |                               |
|   |   | APPLICANT: <b>Olivier LUHN et al.</b>   |                       |                              |       |              |                               |
|   |   | FILING DATE:<br><b>July 13, 2001</b>  |                       | GROUP: <b>1711</b>           |       |              |                               |
| <b>U.S. PATENT DOCUMENTS</b>  |   |   |                       |                              |       |              |                               |
| Examiner<br>Initial   |   | DOCUMENT<br>NUMBER  | DATE                  | NAME                         | CLASS | SUB<br>CLASS | FILING DATE IF<br>APPROPRIATE |
|   |   | <b>5.618.562</b>  | <b>Oct. 17, 1995</b>  | <b>Freund<br/>Industrial</b> |       |              |                               |
|   |   | <b>5.006.345</b>  | <b>April 9, 1991</b>  | <b>Lang<br/>Siegfried</b>    |       |              |                               |
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| <b>FOREIGN PATENT DOCUMENTS</b>   |   |   |                       |                              |       |              |                               |
|   |   | DOCUMENT<br>NUMBER  | DATE                  | COUNTRY                      | CLASS | SUB<br>CLASS | TRANSLATION<br>Yes No         |
|   |   | <b>GB 2093052</b> ✓   | <b>Aug. 25, 1982</b>  | <b>U.K.</b>                  |       |              |                               |
|   |   | <b>GB 833.458</b> ✓   | <b>April 27, 1960</b> | <b>U.K.</b>                  |       |              |                               |
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|   |   |   |                       |                              |       |              |                               |
| <b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>   |   |   |                       |                              |       |              |                               |
|   | ✓ | HILL PM: "STARCH PASTE GRANULATIONS..." Journal of Pharmaceutical Sciences, vol. 65, no. 2, 1976, pages 313-314   |                       |                              |       |              |                               |
|   | ✓ | Tadashi MAKINO et al : "IMPORTANCE OF GELATINIZATION DEGREE OF STARCH PAST..." Chemical and Pharmaceutical Bulletin, JP, vol. 43, no. 3, 1 mars 1995, pages 514-516,    |                       |                              |       |              |                               |
|   | ✓ | VISAVARUNGROJ N et al : "CROSSLINKED STARCH AS BINDING AGENT I. CONVENTIONAL WET GRANULATION" International Journal of Pharmaceutics, vol. 59, no.1, 1990, pages 73-78, |                       |                              |       |              |                               |
|   | ✓ | M.O. Bode-Tunji and K.T. Jaiyeoba : "The effect of starch and surfactants on the granulation of soluble and insoluble powders, 1984, p 190-192,                         |                       |                              |       |              |                               |
|   | ✓ | L.S.C. Wan and K.D Lim : "Granulation of mixtures of lactose and starch by a fluidized bed technique", 1991, p 285-293,   |                       |                              |       |              |                               |
|   | ✓ | A. Stamm and C. Mathis : "Les excipients pour compression directe", 1976, p 237-246,  |                       |                              |       |              |                               |
|   | ✓ | Extrait de la Pharmacopée, 1997, p 1111-1112.   |                       |                              |       |              |                               |
| Examiner  |   |   |                       | DATE CONSIDERED              |       |              |                               |
| * EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609 ; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |   |   |                       |                              |       |              |                               |

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